**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
WASHINGTON, D.C. 20460

# MEMORANDUM

**DATE:** April 29, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

**SUBJECT:** Science Review in Support of the Registration of NT-7815, Containing 0.7% 1-Methylcyclopropene (1-MCP) as its Active Ingredient.

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|---|---|
| **Decision Number:** | 509921 |
| **DP Number:** | 431503 |
| **EPA File Symbol Number:** | 2792-TO |
| **Chemical Class:** | Biochemical |
| **PC Code:** | 224459 |
| **CAS Number:** | 3100-04-7 |
| **Active Ingredient Tolerance/Exemption:** | 40 CFR 180.1220 |
| **MRID Numbers:** | 49739101-49739110 |
| **PRIA Code:** | B672 |

**FROM:** Angela L. Gonzales, Biologist /s/
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

**THROUGH:** Russell S. Jones, PhD, Senior Scientist /s/
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

**TO:** Gina Burnett, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

## ACTION REQUESTED

On behalf of Decco U.S. Post-Harvest, Inc., SciReg, Inc. requests registration of NT-7815, an end-use product (EP) intended for use to counteract postharvest ethylene responses in fruits and vegetables stored in enclosed areas, such as controlled atmosphere storage rooms, coolers, shipping containers, etc. In support of the registration, the applicant has submitted a proposed product label, Confidential Statements of Formula (CSFs) dated 01-22-16 and product chemistry, mammalian toxicology and nontarget organism toxicology data and information. Additional information was provided in an email from F. Smith to G. Burnett dated 1-22-16 and in a supplemental submission dated 4/28/16.

1-MCP
PC Code: 224459
Type of Review: Product Chemistry, Human Health

DP Number: 431503
EPA File Symbol No.: 2792-TO

## RECOMMENDATIONS AND CONCLUSIONS

**1. The product chemistry submission is UNACCEPTABLE, but upgradeable, upon submission and review of the data listed below.**

MRID 49739101: ACCEPTABLE
MRID 49739102: ACCEPTABLE
MRID 49739103: ACCEPTABLE
MRID 49739104: ACCEPTABLE
MRID 49739105: ACCEPTABLE
MRID 49739106: ACCEPTABLE
MRID 49739107: ACCEPTABLE
MRID 49739109: ACCEPTABLE
MRID 49739110: ACCEPTABLE

a. Storage stability and corrosion characteristics data were not submitted and are required. The applicant requested to submit these data as a condition of registration.

b. All other product chemistry data requirements have been satisfied at this time.

**2. The mammalian toxicology submission is ACCEPTABLE.**

MRID 49739108: ACCEPTABLE

a. Sufficient rationales were provided to satisfy the Tier 1 human health assessment data requirements.

**3. Nontarget organism toxicology data requirements are not applicable at this time.**

a. Nontarget organism toxicology data requirements do not apply at this time because the product is for indoor uses only.

## STUDY SUMMARIES

### Biopesticide Use Pattern

The proposed EP is a gel-based formulation contained in a water-soluble bag or in a capsule. The pouches or capsules are placed into an activated proprietary gas generator unit to which water has been added. Approximately 30 minutes after the product is added to the generator, 1-MCP is released as a gas. The product is only to be used in enclosed areas that are air tight to ensure no gas leakage. NT-7815 is intended to be applied to fruits and vegetables postharvest for a period of 12-24 hours, depending on the crop. The application rate is 1-3 applications at a maximum use rate of 1 ppm (volume/volume in air).

### Product Chemistry (MRIDs 49739101-49739107, 49739109-49739110, email to G. Burnett dated 1-22-16)

Aside from the storage stability and corrosion characteristics data requirements, sufficient information has been submitted to satisfy the product chemistry data requirements. The physical and chemical properties of the proposed EP are summarized in Table 1 below. Refer to the Confidential Appendix (CA) below for a summary of data and information submitted to satisfy the other product chemistry data requirements. Data Evaluation Records (DERs) were not created for the submitted data.

| TABLE 1. Physical and Chemical Properties of NT-7815 (40 CFR § 158.2030) | | | |
|---|---|---|---|
| **OCSPP Guideline** | **Property** | **Description of Result** | **MRID** |
| 830.6302 | Color | Off-white | 49739104<br>49739106 |
| 830.6303 | Physical State | Viscous liquid | 49739104<br>49739106 |
| 830.6304 | Odor | Mild, chemical-like | 49739104<br>49739106 |
| 830.6313 | Stability to Normal and Elevated Temperatures, Metals and Metal Ions | Not required for EP | 49739104 |
| 830.6315 | Flammability | > 100 °C | 49739104<br>49739107 |
| 830.6317 | Storage Stability | **Request to submit data as a condition of registration** | |
| 830.6319 | Miscibility | Waived: product is not to be diluted with petroleum solvents | 49739104 |
| 830.6320 | Corrosion Characteristics | **Request to submit data as a condition of registration** | |
| 830.7000 | pH | 5.95 | 49739104<br>49739107 |
| 830.7050 | UV/Visible Light Absorption | Not required for EP | |
| 830.7100 | Viscosity | 3610.1 cSt at 20°C<br>1542.8 cSt at 40 °C | 49739104<br>49739107 |
| 830.7200 | Melting Point/Range | Not required for EP | |
| 830.7220 | Boiling Point/Range | Not required for EP | |
| 830.7300 | Density | 1.0122 g/mL at 20°C | 49739104<br>49739106 |
| 830.7520 | Particle Size, Fiber Length and Diameter Distribution | Not required for EP | |
| 830.7550<br>830.7560<br>830.7570 | Partition Coefficient (n-Octanol/Water) | Not required for EP | |
| 830.7840 | Water Solubility | Not required for EP | |
| 830.7950 | Vapor Pressure | Not required for EP | |

## Mammalian Toxicology (MRIDs 49739108, supplemental submission dated 4/28/16)

Note: DERs were not created for the submitted data.

*1-MCP*

To satisfy the Tier 1 human health assessment data requirements, rationales were submitted or existing data were cited. Data were cited (data matrix dated 01-22-16) to satisfy the following data requirements: acute

inhalation toxicity, 90-day inhalation toxicity, prenatal developmental toxicity, bacterial reverse mutation and *in vitro* mammalian cell assay. The remaining data requirements were satisfied via waiver request or rationale based on the physical nature of the active ingredient (1-MCP is a gas) which precludes certain testing (e.g. acute oral toxicity) and that exposure via all routes is expected to be minimal. The product is only used in a commercial setting that must be airtight and workers are not likely to be significantly exposed to the a.i. because of the following: 1) the product's ingredients are contained within water-soluble pouches or gel capsules which are placed directly into the gas generator; 2) workers must leave the area once the product is applied; 1-MCP isn't released until approx. 30 minutes after application; 3) the treatment area is sealed and should be airtight; 4) workers are not allowed into the treatment area after treatment begins and until treatment ends and the room has been vented for a minimum of 30 minutes; 5) if workers are present in the area during treatment, they must wear appropriate PPE; and 6) cited residue data indicate that 1-MCP degrades rapidly in the atmosphere and that residues of 1-MCP are expected to be low. The use and application rate of the proposed EP are similar to that of currently registered products and fall within the scope of the Agency's current risk assessments on 1-MCP which indicate no risks of concern.

*NT-7815*

To satisfy the acute toxicity data requirements on the EP, rationales were submitted which were primarily based on the lack of significant human exposure based on the formulation and use of the product. As discussed previously in this document, significant human exposure to the a.i. is not anticipated. Significant exposure to the EP is also not anticipated for practically the same reasons as discussed for the active ingredient. Additionally, in the applicant's 04-28-16 supplemental submission, it is stated that the inert ingredients remain in the water when the EP is applied and 1-MCP is released. The preliminary analysis data on the EP support the claim.

**Table 2. Mammalian Toxicology Data for NT-7815 (40 CFR § 158.2050)**

| Study/OCSPP Guideline No. | Results | Toxicity Category/Description | MRID |
|---|---|---|---|
| Acute oral toxicity (rat) (870.1100) | Sufficient rationale provided: significant human exposure is not anticipated based on the product's formulation and use pattern. | - | 49739108 |
| Acute dermal toxicity (rabbit) (870.1200) | Sufficient rationale provided: significant human exposure is not anticipated based on the product's formulation and use pattern. | - | 49739108 |
| Acute inhalation toxicity (rat) (870.1300) | Sufficient rationale provided: significant human exposure is not anticipated based on the product's formulation and use pattern. | - | 49739108 |
| Primary eye irritation (rabbit) (870.2400) | Sufficient rationale provided: significant human exposure is not anticipated based on the product's formulation and use pattern. | - | 49739108 |
| Primary dermal irritation (rabbit) (870.2500) | Sufficient rationale provided: significant human exposure is not anticipated based on the product's formulation and use pattern. | - | 49739108 |
| Dermal sensitization (guinea pig) (870.2600) | Sufficient rationale provided: significant human exposure is not anticipated based on the product's formulation and use pattern. | - | 49739108 |

## CONFIDENTIAL APPENDIX

## STUDY SUMMARIES

**Product Chemistry (MRIDs 49739101-49739107, 49739109-49739110, email to G. Burnett dated 01-22-16)**

NT-7818 is an end-use product comprised of the following:

- 1-MCP as the active ingredient at 0.7%, by weight

[redacted]

cc: A. L. Gonzales, G. Burnett, BPPD Science Review File, IHAD/ARS
A. L. Gonzales, Biologist, FT, PY-S: 4/29/16

***Manufacturing process information may be entitled to confidential treatment***